UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,075	01/23/2004	Thomas Briese	0019240.00447US2	7998

56949 7590 04/16/2007
WilmerHale/Columbia University
399 PARK AVENUE
NEW YORK, NY 10022

EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,075	BRIESE ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-32 and 34-75* is/are pending in the application.

4a) Of the above claim(s) *11-24,46-60 and 62-75* is/are withdrawn from consideration.

5)☒ Claim(s) *45 and 61* is/are allowed.

6)☒ Claim(s) *1-6,8-10,25-32 and 34-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 December 2006 has been entered.

The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Louise Humphrey, Art Unit 1648.

This Office Action is in response to the amendment filed 27 December 2006. Claims 7 and 33 have been cancelled. New claims 39-75 have been added. Claims 1-6, 8-32, and 34-75 are pending. Claims 11-24, 46-60, and 62-75 are withdrawn. Claims 1-6, 8-10, 25-32, 34-45, and 61 are examined.

New Matter Rejection - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-10, 25-32, and 34-44 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This is a New Matter rejection.

The terms not supported by the original disclosure or claim as filed are "from 13 to about 30 consecutive nucleotides of SEQ ID NO:43" (as recited in claims 1-6, 8-10, 25-32, and 34-38), "from 19 to about 30 consecutive nucleotides of SEQ ID NO:43" (as recited in claims 39 and 40), and "from 19 to about 28 consecutive nucleotides of SEQ ID NO:43" (as recited in claims 41 and 42).

Applicant's amendment, filed 12 September 2006, directs to support in paragraphs 10, 28, 29, 32, 33, 38, 45 and 46, and asserts that the amendment raises no new matter. However, the specification as filed does not provide sufficient written description of the above-mentioned "limitations". The specification does not provide sufficient support for the specifically claimed length of nucleotides of SEQ ID NO:43. The specification only disclose a synthetic nucleic acid sequence comprising 10-30 consecutive nucleotides of at least one of the following: (a) the N gene region of the SARS-associated coronavirus genome; and (b) the 3' non-coding region of the SARS-associated coronavirus genome (see ¶9), which is further disclosed in the embodiment of a synthetic nucleic acid sequence comprising 10-30 consecutive nucleotides of the nucleic acid sequence of SEQ ID NO: 1 or of a nucleic acid sequence that is complementary to the nucleic acid sequence of SEQ ID NO: 1 (see ¶11).

The instant claims now recite 13 to about 30, 19 to about 30, or 13 to about 28 consecutive nucleotides of a different sequence, SEQ ID NO:43, which were not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims as originally filed. Applicant's reliance on a generic disclosure, 10-30 consecutive nucleotides of at least one of the following: (i) the N gene region of the SARS-associated coronavirus genome; and (ii) the 3' non-coding region of the SARS-associated coronavirus genome, do not provide sufficient direction and guidance to the features currently claimed (13 to about 30 consecutive nucleotides). It is noted that a generic or a subgeneric disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith* 173 USPQ 679 683 (CCPA 1972) and MPEP §2163.05.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. §112. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP §714.02, 2163.05-06 and 2173.05 (i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-10, 25-32, 34-45, and 61 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the sequence consisting of 13 to about 30 consecutive nucleotides of SEQ ID NO:43 or the sequence consisting of SEQ ID NO:2, does not reasonably provide enablement for a sequence consisting of 13 to about 30 consecutive nucleotides of SEQ ID NO:43 or a sequence consisting of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. . See, *In re Wands*, 8 USPQ2d 1400, at 1404 (CAFC 1988); and *Ex Parte Forman*, 230 U.S.P.Q. 546 (BPAI 1986).

The claims are drawn to a sequence consisting of from 13 to about 30, from 19 to about 30, and from 19 to about 28 consecutive nucleotides of a nucleic acid sequence. Claims 1-6, 8-10, 25-32, 34-45, and 61 make reference to "a sequence" or "a nucleic acid." The phrases can be interpreted as comprising the full length SEQ ID NO or any portion thereof. Thus, the claims encompass nucleotide sequences that are smaller

than 13 to about 30 consecutive nucleotides of SEQ ID NO:43 or the full length SEQ ID NO:2, such as a trinucleotide. However, a trinucleotide would not be able to determine the presence or absence of SARS-associated corona virus in a biological sample. The specification only supports the sequences consisting of 10-30 consecutive nucleotides of SEQ ID NO:1. Any nucleotide as small as a trinucleotide binds nucleotide sequence in a biological sample in non-specific manner and would not have any SARS-detection function as disclosed in the present specification.

This rejection can be obviated by amending the claims to read "a synthetic nucleic acid which has the sequence ..."

Response to Arguments

Claim Rejections - 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. §102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. §102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. §102(e)).

The rejection of claims 1, 2, 4, 5, 8, 25, 27, 29 and 35 under 35 U.S.C. §102(b) as being anticipated by Fodor *et al.* (US 2001/0053519) is **withdrawn** in view of the amendment with the new limitation "from 13 to about 30 consecutive nucleotides of SEQ ID NO: 43" in the claim.

The rejection of claims 1, 4 and 7-10 under 35 U.S.C. §102(a) as being anticipated by Genbank locus AY274119 (nucleotides 28491-29630, publicly available on April 14, 2003) is **withdrawn** in view of the Declaration under 37 C.F.R. §1.131 by the Applicants.

The rejection of claims 1-6, 8, 9, 25-32 and 34-38 under 35 U.S.C. §102(e) as being anticipated by Rappuoli *et al.* (WO 2004/092360, filing date 14 April 2003) is **withdrawn** in view of the Declaration under 37 C.F.R. §1.131 by the Applicants.

The declaration filed on 12 September 2006 under 37 CFR §1.131 is sufficient to overcome the Rappuoli reference and the Genbank Accession No. AY274119. The declaration consists of a copy of an e-mail from Dr. Briese to TIB Molbiol, LLC confirming the production of primers and primer sets of the invention prior to April 12, 2003 and a copy of a laboratory notebook page showing a picture of an agarose gel that points to PCR products generated using primers of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 31 and 32 under 35 U.S.C. §103(a) as being obvious over Fodor *et al.* (US 2001/0053519) is **withdrawn** in view of the amendment with the new limitation "from 13 to about 30 consecutive nucleotides of SEQ ID NO: 43" in the claim.

The rejection of claims 1-6, 8, 9, 25-32, 34, 35, and 38 under 35 U.S.C. §103(a) as being obvious over Ksiazek *et al.* (10 April 2003), Genbank Accession No. AY274119 (publicly available on 12 April 2003), and either Vabret *et al.* (2001) or Stewart *et al.* (1995) is **withdrawn** in view of the Declaration under 37 C.F.R. §1.131 by the Applicants, as indicated above.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Humphrey, Ph.D.
Assistant Examiner
01 April 2007

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600